

BIOTRUST FREQUENTLY ASKED QUESTIONS

How Does the BioTrust Protect Your Privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. Blood spots are stored using a code and not a person's name. Details that could pinpoint a child or family are removed. The Department of Health and Human Services (MDHHS) has been granted the highest level of protection, a Certificate of Confidentiality from the United States Department of Health and Human Services.

Blood spots are separated from the newborn screening card and labeled with a storage code, then sent to the Michigan Neonatal Biobank for storage.



Requests for blood spots and data must be approved by MDHHS Institutional Review Board, BioTrust Scientific Advisory Board and MDHHS Programs.



Michigan Neonatal Biobank replaces storage code with a research code. Blood spots labeled with the research code given to researcher.



1 After newborn screening is completed, the filter paper containing left-over blood spots is separated from the newborn screening card that has the baby's directly identifiable information. A code is assigned to five remaining blood spots before transfer to the Michigan Neonatal Biobank for storage. The same code is applied to the sixth blood spot that remains in the State Lab for storage in case a parent or person (over 18 years) needs the spot. The Michigan Neonatal Biobank can not access and does not receive any directly identifiable information.

2 Research requests are reviewed and approved by the MDHHS Institutional Review Board and Scientific Advisory Board to ensure protection of human subjects. Both boards must approve a study before blood spots are released. If a research study requires samples meeting certain criteria or asks for accompanying data, the MDHHS Program housing the data must approve its release. MDHHS will then conduct database linkages to select the right blood spots while still keeping blood spots and data confidential and coded.

3 Once MDHHS identifies the blood spots and potential data required for an approved study, the Biobank receives a list of storage codes to retrieve blood spots for the study. Before the blood spots and potential coded data are released to a researcher the Biobank assigns another, different code. Thus, the code a researcher sees is two steps removed from the original newborn screening card number.

Researchers requesting identified blood spots or data must get consent from subjects for use in the specific study.

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What are Your Options?

*For more details on your consent options please visit the “Consent” page on the BioTrust website.
(www.michigan.gov/biotrust)*

Were you or your child born in Michigan before July 1984?

Blood spots received by the State Laboratory on infants born before July 1984 have been destroyed.

Were you or your child born in Michigan between July 1984 and May 1, 2010?

Today, blood spots from over four million people are stored. Blood spots collected between July 1984 and May 1, 2010, are coded and may be used in health research under a waiver of informed consent granted by the Michigan Department of Health and Human Services (MDHHS) Institutional Review Board. These blood spots may also be requested by a parent or person (>18y) for their own use. If you want to continue to allow the use of coded blood spots in health research, you do not need to do anything. If you do not want your or your child's blood spots made available for future health research you have two options to **opt-out**. You may fill out a form to: (1) request that blood spots remain stored but not used in future research, or (2) request that blood spots be destroyed. The lab requires verification that you are the legal representative entitled to make the request to destroy blood spots. You must submit your State ID or driver's license as well as a copy of your child's birth certificate.

Michigan Department of Community Health
Directive to Destroy Residual Newborn Screening Blood Specimen

Child's Name at Birth: _____ Date of Birth: _____
Child's Current Name: _____ Circle Mark Order of Multiple Births: 1st 2nd 3rd 4th 5th
Mother's Name at Time of Child's Birth: _____ Hospital of Birth: _____

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy any child's (or any one's) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

Signature of parent, guardian, or other legal representative: _____ Relationship to child: _____
Printed name: _____ Date: _____
Street Address: _____ City: _____ Zip: _____ Phone: _____

* "Legal representative" means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the parent(s) signing this form must be authenticated. Please attach a copy of:
1) the child's birth certificate and 2) either's: Bureau, state-issued identification card, or passport of parent(s) who signed above. Additional identifying documents may be requested.

Mail completed form with required copies to:
Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 10045
Lansing, MI 48909

Please state why you are making this request. (This will help improve the newborn screening program, but you do not have to complete this section.)
☐ Privacy concerns ☐ Not comfortable with research ☐ Other: _____

Authority: ☐ Michigan Public Health Code, Act 368 of 1978 ☐ The Michigan Department of Community Health is in equal opportunity employment, services, and program provider.

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Was your child born in Michigan after April 30, 2010?

Blood spots from an infant born after April 30, 2010, will be stored indefinitely (forever) after newborn screening is done. However, the blood spots will not be used in research through the BioTrust unless a signed parental consent form is on file with the State Laboratory. New parents are given a BioTrust consent form to record whether “yes” they want blood spots made available for research or “no” they do not. One full blood spot will still be saved for future use by the child or family, should it ever be needed.

Please note, if a parent declines participation in the BioTrust, blood spots are still stored unless a form to destroy the blood spots is returned to the State Laboratory.

After Newborn Screening
Your Baby's Blood Spots

Michigan BioTrust for Health

Facts and Choices You Need to Understand

Yes, my baby's blood spots may be used for research. ☐ No, my baby's blood spots may not be used for research. ☐

There is no penalty for saying no.

State: _____ Date: _____

To make a personal choice about blood spot use, please contact the Michigan Department of Health and Human Services.

Call 1-866-673-9939 or Email biotrust@michigan.gov

www.michigan.gov/biotrust